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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,258	12/09/2003	James M. Peck	VTN-632	4704
27777	7590	12/31/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			VARGOT, MATHIEU D	
			ART UNIT	PAPER NUMBER
			1791	
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			12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,258	Applicant(s) PECK ET AL.	
	Examiner Mathieu D. Vargot	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-26 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-26 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Claims 1, 2 and 6-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claim 1 to recite that the additive "is not glycerol monostearate" and there is no support for this amendment. Applicant can specify what the additive is in a claim and can cancel the additive from a Markush group, if desired. However, negative limitations—ie, the express exclusion of a particular additive—require clear support in the specification. Since glycerol monostearate is **clearly used as an additive in the instant specification**, it is submitted that applicant does not have support to exclude it from the claims in the instant manner.

2. Claims 1, 2, 6-26 and 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 49, the occurrence of "medical device" at line 4 should be changed to —ophthalmic device—to agree with the preamble. In claim 1, line 5, "the polymer..." should be —a polymer...-- in that such has not been previously set forth. Also, it should be clarified that the molded base is in fact molded from the polymer rubber or plastic. Claim 49 also needs to be clarified. As it stands, the molded base comprises glycerol monostearate, not a polymer with a glycerol monostearate additive.

Art Unit: 1791

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by British Patent Application 2,078,760 generally for reasons already set forth in paragraph 3 of the previous action noting the following.

The rejection has been maintained in view of the new matter rejection made in paragraph 1, supra. I.e., given that the amendment made to claim 1 is new matter, the claims are still validly rejected under 102 over the applied reference.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-19 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over British Patent Application 2,078,760 essentially for reasons of record noting the following.

As noted in the previous action, the exact surface roughness of the package would have been within the skill level of the art dependent on the exact properties desired for the inner wall. Clearly, the inner wall of British –760 would have some degree of surface roughness and the exact degree of roughness would have been obvious and readily determined through routine experimentation by one of ordinary skill in the art dependent

on the desired surface texture. Hence, newly added claims 49-51 are submitted to be obvious over British -760. British -760 discloses the concentration of the monostearate to be in the range of 1-1.5%, such being within the range set forth in instant claim 50 and such submitted to render a concentration of "about 2%" to be obvious thereover.

5. Claims 1, 2 and 6-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese document 52-93398 in view of Neeffe (col.2, lines 36-41). Japanese document -398 is applied essentially for reasons of record as set forth in the previous action, the reference failing to teach that the PVP additive is added to the polymer prior to molding the base—ie, the reference teaches to coat the already molded container with the PVP. However, Neeffe provides a teaching to one of ordinary skill in this art that coating already formed molds would be equivalent to adding the coating material to the polymer prior to making it into the mold—see column 2, lines 36-41. While this teaching is disclosed with respect to a release agent, it is submitted that it would have applicability to whatever additive one desires to incorporate into a plastic article. In other words, one of ordinary skill in the art would know that the additive would be incorporated either by mixing and molding with the base material and then making the article therefrom or by coating the base material once it has been formed into the final article. In view of the teaching of Neeffe, it is submitted that one of ordinary skill in the art would have found it obvious to have simply compounded the PVP with the polypropylene that forms the beaker prior to molding same into the beaker in the process of Japanese -398. This would quite possibly allow for an extended use period for the beaker without having to apply additional PVP coatings on a regular basis.

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

In view of the amendment, Neefe has been additionally applied to teach the equivalency of compounding a (release) additive with a polymer and then molding it into an article and coating an already molded polymer article with the additive. Neefe has been combined with Japanese document –398, which teaches the PVP coating. Concerning the glycerol stearate embodiment, the amendment to claim 1 is considered to be new matter and hence the 102 was maintained. At any rate, newly added claims 49-51, which call for using a glycerol monostearate, are considered to be obvious over British –760 for the reason given supra—the exact surface roughness of the article would have been within the skill level of the art. Clearly, it has to have some degree of roughness and the exact value would have depended on final use for the package and the roughness of the mold used to make it. Applicant submits that Japanese –398 and British –760 do not roughen the container. However, the instant claims are product claims and not method claims and hence it is immaterial whether the references actually teach a step of roughening, as long as the containers/packages have some degree of roughness, which it is submitted they would. The instant roughness –on the micron scale—is conventionally considered to be fairly smooth, not rough. I.e., to get such a smoothness, it is likely that then molds or packages made therefrom would have to be polished to some extent, not roughened as argued by applicant.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mathieu D. Vargot whose telephone number is 571 272-1211. The examiner can normally be reached on Mon-Fri from 9 to 6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson, can be reached on 571 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1791

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

M. Vargot
December 22, 2007

M. Vargot
Mathieu D. Vargot
Primary Examiner
Art Unit 1791

12/22/07